K082965

OCT 23 2008

APPENDIX C

SUMMARY OF SAFETY AND EFFICACY

(Per 21 CFR Part 807.92)

I. GENERAL INFORMATION

Device Generic Name: Infrared Lamp

Trade Name: Luminex Infrared Lamp System

Device Classification: Class II, Performance Standards
21CFR Part 890.5500 - Lamp, Infrared, Therapeutic Heating

Product Code: ILY

Applicant Name and Address:
Medical Laser Systems, Inc.
20 Baldwin Drive
Branford, CT 60405
203 / 481-2395
Brian D. Richardson, President

Key Contact:
Miki Kolton, Regulatory Consultant
Greenberg, Traurig, LLP
800 Connecticut Ave NW Suite 500
Washington, DC 20006
202-331-3100

510(k) Number: Pending

II. DEVICE DESCRIPTION

The Luminex Infrared Lamp System is an AC operated, non-invasive, therapeutic medical device that provides continuous heat therapy through the use of infrared and visible laser diodes. The system consists of a Control Unit that houses the electronics and controls, and treatment probes that contain the infrared and visible laser diodes. The probes are intended to be placed directly on the skin to provide topical heating.

III. INDICATIONS FOR USE

The Luminex Infrared Lamp System is intended to emit energy in the visible and near infrared spectrum to provide topical heating for the purpose of elevating

tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm; the temporary increase in local blood circulation; and/or the temporary relaxation of muscle.

IV. Predicate Devices

Predicate devices to the Luminex Infrared Lamp System include, but are not limited to, the Thor DDII IR Lamp System (K033923), the Maestro MDTL Laser System (K053473), and the Vectra Genisys Laser System (K040662).

V. Summary of the Technical Characteristics of the Luminex System as Related to the Referenced Predicate Devices.

The Luminex Infrared Lamp System and the aforementioned predicate devices are infrared lamps as defined in 21 CFR 890.5500. These devices utilize infrared and visible diodes to generate topical heating for the purpose of elevating tissue temperatures for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, the temporary increase in local circulation and the temporary relaxation of muscle. The Luminex Infrared Lamp System and the aforementioned predicate devices have the same intended uses and similar technical and performance characteristics.

VI. Testing

Testing of the Luminex Infrared Lamp System includes functional performance testing and electrical safety testing in accordance with all applicable standards for Infrared Lamp Systems of this type.

VII. Conclusions

Pursuant to the testing and comparison to the predicate devices, the Luminex Infrared Lamp System has the equivalent intended uses, with similar technical and performance characteristics. The Luminex Infrared Lamp System complies with the generally accepted therapeutic heat performance specifications by producing a level of tissue temperature reported in the literature and accepted by the Federal Food and Drug Administration.

The Luminex Infrared Lamp System performs as intended and does not raise any new safety or efficacy issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 23 2008

Medical Laser Systems, Inc.
% Greenberg, Traurig, LLP
Ms. Miki Kolton
800 Connecticut Avenue NW, Suite 500
Washington, District of Columbia 20006

Re: K082969
Trade/Device Name: Luminex Infrared Lamp System
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: September 22, 2008
Received: October 8, 2008

Dear Ms. Kolton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

APPENDIX A

Indications for Use Statement

510(k) Number (if known): Pending

Device Name:

Luminex Infrared Lamp System

Indications for Use:

The Luminex Infrared Lamp System is intended to emit energy in the visible and near infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm; the temporary increase in local blood circulation; and/or the temporary relaxation of muscle.

Prescription Use: X **AND/OR** **Over the Counter Use:** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODpE)

for mkn

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K082969